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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. 98F–0196]

Food Additives Permitted in Feed and Drinking Water of Animals; Selenium Yeast

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for food additives permitted in feed to provide for the safe use of selenium yeast as a source of selenium in animal feeds intended for chickens. This action is in response to a food additive petition filed by Alltech Biotechnology Center.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**]. Submit written objections and requests for a hearing by [*insert date 30 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Nelson Chou, Center for Veterinary Medicine (HFV–228), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0161.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of May 12, 1998 (63 FR 26193), FDA announced that a food additive petition (animal use) (FAP 2238) had been filed by Alltech Biotechnology Center, 3031 Catnip Hill Pike, Nicholasville, KY 40356. The petition proposed to

amend the food additive regulations in § 573.920 *Selenium* (21 CFR 573.920) to provide for the safe use of selenium yeast as a source of selenium in animal feeds intended for use in poultry. The notice of filing provided for a 60-day comment period on the petitioner's environmental assessment. No comments have been received.

II. Conclusion

FDA concludes that the data establish the safety and utility of selenium yeast, for use in feeds for chickens, and the food additive regulations should be amended as set forth below.

III. Public Disclosure

In accordance with § 571.1(h) (21 CFR 571.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Veterinary Medicine by appointment with the information contact person listed above. As provided in § 571.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

IV. Environmental Impact

The agency has determined under 21 CFR 25.32(r) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Objections and Hearing Requests

Any person who will be adversely affected by this regulation may at any time file with the Dockets Management Branch (address above) written objections by [*insert date 30 days after date of publication in the* **Federal Register**]. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing

is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents are to be submitted and are to be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 573

Animal feeds, Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 573 is amended as follows:

PART 573—FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS

1. The authority citation for 21 CFR part 573 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

2. Section 573.920 is amended by revising paragraph (b) and by adding paragraph (h) to read as follows:

§ 573.920 Selenium.

* * * * *

(b) The food additive selenium is a nutrient administered in animal feed as sodium selenite or sodium selenate or in a controlled-release sodium selenite bolus, as provided in paragraphs (f) and (g) of this section, or as selenium yeast, as provided in paragraph (h) of this section.

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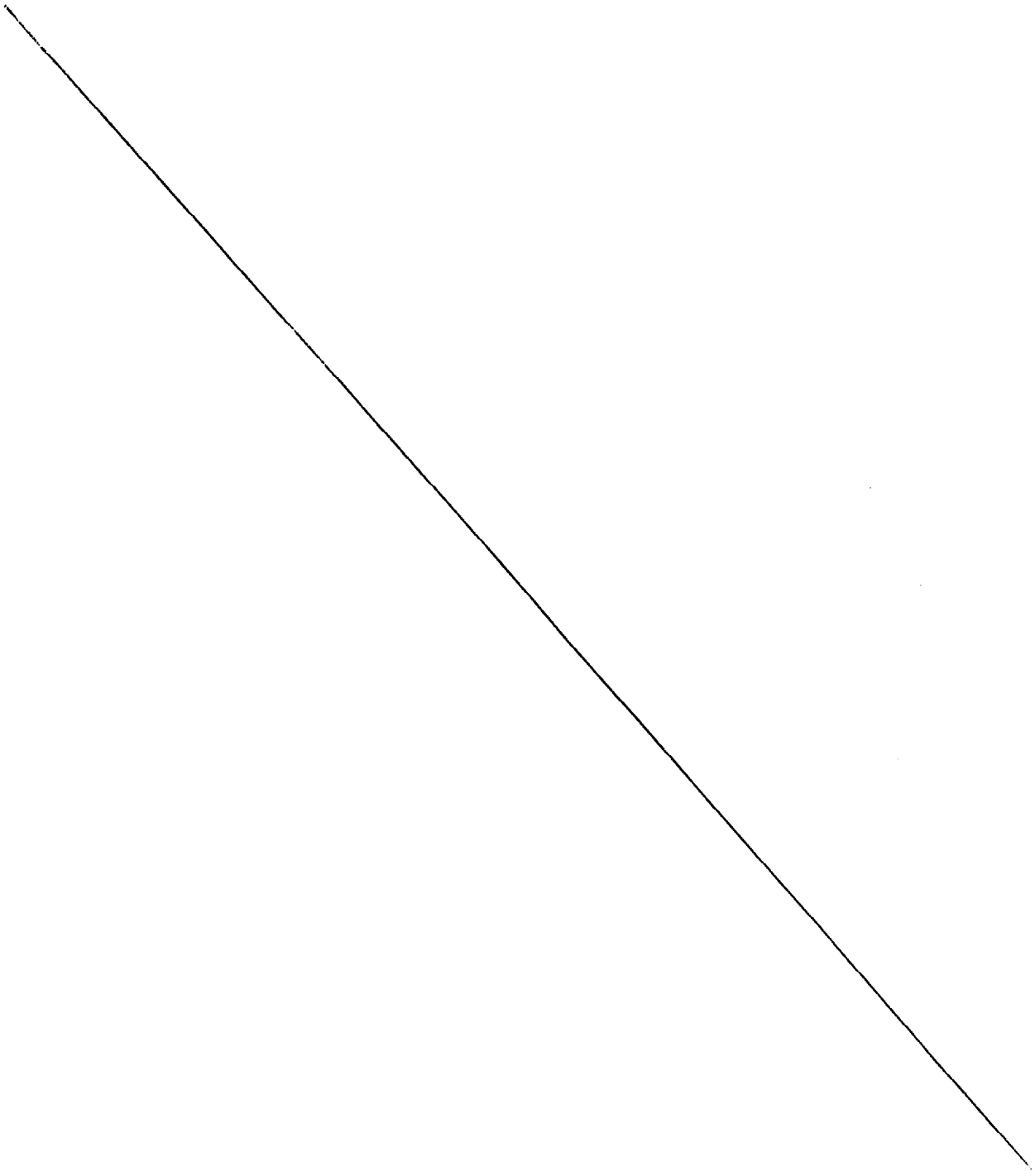

(h) The additive selenium yeast is added to complete feed for chickens at a level not to exceed 0.3 part per million. Usage of this additive must conform to the requirements of paragraphs (e) and (f) of this section.

Dated: 5/26/00
May 26, 2000

Andrew J. Beaulieu
Acting Director
Center for Veterinary Medicine

[FR Doc. 00–???? Filed ??–??–00; 8:45 am]

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